510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

The assigned 510(k) number is K121790

Submitted By:
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SEP 2 5 2013

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Date Prepared:
September 23, 2013

Device Name:
Proprietary / Trade Name: Access AccuTnI+3 Reagent for use on the UniCel DxI Access Immunoassay Systems
Common Name: Troponin I Enzyme Immunoassay
Classification Name: Immunoassay, Troponin Subunits
Classification Regulation: 21 CFR 862.1215
Product Code: MMI

Proprietary / Trade Name: Access AccuTnI+3 Calibrator
Common Name: Calibrator
Classification Name: Calibrator
Classification Regulation: 21 CFR 862.1150
Product Code: JIT

Proprietary / Trade Name: UniCel DxI 800 Access Immunoassay System
Common Name: Discrete photometric chemistry analyzer for clinical use Classification Name: Discrete photometric chemistry analyzer for clinical use
Classification Regulation: 21 CFR 862.2160
Product Code: JJE

Predicate Device:
The Access AccuTnI+3 Reagent and AccuTnI+3 Calibrators for use on the UniCel DxI Access Immunoassay Systems claim substantial equivalence to the TnI-Ultra™ Assay and ADVIA Centaur TnlUltra Calibrators for the Siemens ADVIA Centaur® System, FDA 510(k) Number K053020, cleared December 30, 2005.

The UniCel DxI 800 Access Immunoassay System claims substantial equivalence to the UniCel DxI 800 Access Immunoassay System (K023764), cleared January 28, 2003.

Device Description:
The Access AccuTnI+3 Reagents, AccuTnI+3 Calibrators and the UniCel DxI 800 Access Immunoassay System compose the Access Immunoassay System for the quantitative determination of cardiac troponin I (cTnI) in human serum and plasma.

The Access AccuTnI+3 Reagent packs contain specific reagents for the *in vitro* diagnostic measurement of cTnI including:

- Paramagnetic particles coated with mouse monoclonal anti-human cardiac troponin I (cTnI) suspended in TRIS buffered saline, with surfactant, bovine serum albumin (BSA) matrix, < 0.1% sodium azide, and 0.1% ProClin® 300.
- 0.1N NaOH
- TRIS buffered saline, surfactant, < 0.1% sodium azide and 0.1% ProClin 300.
- Mouse monoclonal anti-human cTnI alkaline phosphatase conjugate diluted in ACES buffered saline, with surfactant, BSA matrix, protein (bovine, goat, mouse), < 0.1% sodium azide, and 0.25% ProClin 300.

The Access AccuTnI+3 Calibrator set contains multi-point calibrators for use with the Access AccuTnI+3 assay. Each vial contains zero and approximately 0.2, 0.9, 3.7, 20 and 80 ng/mL (µg/L) of recombinant cardiac troponin I complex, respectively, in a buffered BSA matrix, with surfactant, < 0.1% sodium azide, and 0.1% ProClin 300.

the UniCel DxI 800 Access Immunoassay System is an *in vitro* diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

Intended Use:
The Access AccuTnI+3 Reagent for use on the UniCel DxI Access Immunoassay Systems is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Acess Immunoassay Systems to aid in the diagnosis of myocardial infarction.

The Access AccuTnI+3 Calibrators for use on the UniCel DxI Access Immunoassay Systems are intended to calibrate the Access AccuTnI+3 Reagent for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay Systems to aid in the diagnosis of myocardial infarction.

The UniCel DxI 800 Access Immunoassay System is an *in vitro* diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

Comparison to the Predicate:
The Access AccuTnI+3 Reagent and Access AccuTnI+3 Calibrators for use on the UniCel DxI Access Immunoassay Systems and the predicate device, ADVIA Centaur® TnI-Ultra™Assay and ADVIA Centaur TnI-Ultra Calibrators, were compared. The information for the predicate device was derived from the predicate device 510(k) Summary and product labeling.

Similarities between the Access AccuTnI+3 Reagent and Calibrator and the Predicate

Characteristic	**Predicate Device ADVIA Centaur® TnI-Ultra™ K053020**	**New Device Access AccuTnI+3**
Intended Use	An *in vitro* diagnostic method for the quantitative measurement of cardiac TnI in serum and plasma to aid in the diagnosis of myocardial infarction.	same
Assay Principle	Chemiluminescent sandwich immunoassay	same
Test System	Automated immunoassay instrument	same
Sample Type	Serum and heparinized plasma	same
Reagent Pack configuration	Reagents ready to use and separated in a single reagent pack	same
Primary Reagent Materials	Solid phase magnetic particles, anti- cTnI antibodies	same

Differences between the Access AccuTnI+3 Reagent and Calibrator and the Predicate

Characteristic	**Predicate Device ADVIA Centaur® TnI-Ultra™ K053020**	**New Device Access AccuTnI+3**
Sample Type	EDTA plasma	No EDTA plasma claim
Immunoassay Instrument	ADVIA Centaur	UniCel DxI Immunoassay System
Calibrator Materials	Bovine cTnI in goat serum	Recombinant troponin complex in buffered BSA
Calibrators: number and type	Two Lyophilized : high and low (use with Master Curve)	Six Liquid: 0 and approximately 0.2, 0.9, 3.7, 20 and 80 ng/mL with no master curve
Specific Reagent Materials	Polyclonal goat anti-cTnI antibody labeled with acridinium ester, 2 biotinylated mouse monoclonal anti-cTnI antibodies, magnetic particles conjugated with streptavidin	Mouse monoclonal anti-human cTnI alkaline phosphatase conjugate, magnetic particles coated with mouse monoclonal anti-human cTnI
Indications for Use	Cardiac troponin I determinations aid in the diagnosis of acute myocardial infarction and in the risk stratification of patients with non-ST segment elevation acute coronary syndromes with respective to relative risk mortality, myocardial infarction or increased probability of ischemic events requiring urgent revascularization procedures.	No risk stratification indication

Differences between the Access AccuTnI+3 Reagent and Calibrator and the Predicate

Characteristic	Predicate Device ADVIA Centaur® TnI-Ultra™ K053020	New Device Access AccuTnI+3
Sample Volume	100µl	55µl
Analytical Measuring Range	0.008 ng/mL to 50 ng/mL	0.03 ng/mL to 80 ng/mL
Acute Myocardial Infarction (AMI) Cutoff	0.78 ng/mL per WHO-defined cutoff	0.03 ng/mL based on clinical trial outcome
Expected Results (Upper Reference Limit)	99th percentile of 0.04 ng/mL; range of 0.02-0.06 ng/mL	99th percentile upper reference limit (URL) is < 0.03 ng/mL with a 97.5% upper confidence limit of 0.04 ng/mL
Precision	Total CV of 10% at a level of 0.03 ng/mL	Total CV of ≤8% at concentrations >0.075 ng/mL. SD ≤0.006 at concentrations ≤0.075 ng/mL

The UniCel DxI 800 Access Immunoassay System and the previously cleared version of the UniCel DxI 800 Access Immunoassay System were compared.

Similarities between the UniCel DxI 800 Access Immunoassay System and the Predicate

Characteristic	Predicate Device UniCel DxI 800 Access Immunoassay System K023764	New Device UniCel DxI 800 Access Immunoassay System
Indications for Use	The UniCel DxI 800 Access Immunoassay System is an in vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.	same
Operating Principle	Micro computer controlled, random and continuous access	same
Assay Type	Enzyme immunoassays	same
Detection	Chemiluminescent	same
Modules	SPU, sample/reagent storage, pipettor, bulk feeder, analytical, carriage, substrate, pick and place, fluidics, electronic/systems computer, peripheral	same

Differences between the UniCel DxI 800 Access Immunoassay System and the Predicate

Characteristic	Predicate Device UniCel DxI 800 Access Immunoassay System K023764	New Device UniCel DxI 800 Access Immunoassay System
Thermal algorithm capability	Not present	Present
Assay Protocol File (APF)	AccuTnI APF	AccuTnI+3 APF with addition of the thermal algorithm
Software	Version 2.4-4.4	Version 4.5: added capability to implement the thermal algorithm; added result suppression when instrument internal case temperature is outside 18° to 36°C
Operating Temperature	18°C to 32°C ambient	18°C to 30°C ambient 18°C to 36°C instrument case temperature

Conclusion: The information provided above demonstrates that the new device, the Access AccuTnI+3 Reagent and Access AccuTnI+3 Calibrators for use on the UniCel DxI Access Immunoassay System, have the same intended use as the predicate device. The UniCel DxI 800 Access Immunoassay System has the same intended use as the predicate device. In addition, verification and validation testing, the clinical and analytical data, the clinical use of the product reflected in current MI diagnostic guidelines, and other scientific information provided in this submission demonstrate that the Access AccuTnI+3 Reagent, Access AccuTnI+3 Calibrators on the UniCel DxI Access Immunoassay Systems is as safe and effective as the predicate devices. Taken together, this information establishes the substantial equivalence of Beckman Coulter's products to predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Beckman Coulter Inc.
c/o Kerrie Oetter
1000 Lake Hazeltine Dr.
CHASKA MN 55318-1084

Re: K121790
Trade/Device Name: Access AccuTnI+3 Reagent, Access AccuTnI+3 Calibrator, UniCel Dxl 800 Access Immunoassay System
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: II
Product Code: MMI, JIT, JJE
Dated: September 04, 2013
Received: September 11, 2013

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121790

Device Name: Access AccuTnI+3 Reagent, Access AccuTnI+3 Calibrator and UniCel DxI 800 Access Immunoassay Systems

Indications for Use:

The Access AccuTnI+3 Reagent is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay Systems to aid in the diagnosis of myocardial infarction.

The Access AccuTnI+3 Calibrators are intended to calibrate the Access AccuTnI+3 Reagent for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the UniCel DxI Access Immunoassay Systems to aid in the diagnosis of myocardial infarction.

The UniCel DxI 800 Access Immunoassay System is an *in vitro* diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health
Evaluation and Safety
510(k) k121790